May 13, 2009

***** VIA EMAIL *****

National Vaccine Program Office,
U.S. Department of Health and Human Services
200 Independence Avenue, SW., Room 715-H
Washington, DC 20201
Attention: Vaccine Safety RFI.
vaccinesafetyRFI@hhs.gov

SafeMinds is pleased to offer the following in response to the National Vaccine Program Office (NVPO) request for public comment on the National Vaccine Advisory Committee (NVAC) Vaccine Safety Working Group draft Recommendations to the Centers for Disease Control and Prevention’s (CDC) Immunization Safety Office (ISO).

Additionally, we would like to state our appreciation of our inclusion in the public engagement efforts, particularly the inclusion of our Executive Director, Sallie Bernard, in the Salt Lake City Writing Group (SLCWG), as we believe public engagement in the midst of a growing crisis of faith in our immunization program is appropriate and will serve to rebuild trust. We are encouraged these recent efforts by the NVPO and believe that every opportunity to engage the public in this important process is necessary and is aligned with the current administration’s policy for greater public involvement and transparency in government.

In general, we believe the VSWG recommendations must put primary emphasis on a “Safety First” agenda. As noted frequently throughout the public engagement efforts, gaps in vaccine safety research, and safety in general, is a primary concern held by the public. The public’s concern in this sense must not be marginalized, but addressed through the closing of research gaps to restore trust in vaccines. Baseline data on the health outcomes of unvaccinated [and alternatively vaccinated] children should not be optional, but required by basic principles of ethics, scientific curiosity, as expressed in Section 27 of VICA in 1986. It is simply impossible to achieve the goal of safer vaccines, or to assess progress, without having an accurate baseline benchmark for acute and chronic disease in unvaccinated children. Without such basic data, there is no way to know the relationship between acute and chronic disease and adverse reactions caused by vaccines.

As such, SafeMinds applauds the draft’s recognition the need for a study of vaccinated vs. unvaccinated populations. However, we would state that a “feasibility study” falls short of the mark in restoring public trust. The recommendation should be that a comprehensive study of vaccinated vs. unvaccinated populations for long-term effects of vaccines to determine total health outcomes with regard to vaccine toxicants (e.g. – mercury, aluminum, formaldehyde, etc.), possible detrimental effects of current timeline of immunization schedule and the number of vaccines given at any one time be conducted from both a prospective and retrospective manner immediately, as well as on an on-going basis.

There are no special methodological or design issues that make this program of research somehow unique or difficult compared to the remainder of the body of recommended research. Additionally, it is highly ethical to
prospectively study children who self-select for exemptions for religious or philosophical reasons or to retrospectively study such children. We understand that care needs to be taken in the design of the research program to ensure that the cases and controls are sufficiently equivalent in all other aspects for vaccine exposure to make a comparison of their health outcomes meaningful, as well as accounting for possible differences in health services seeking behavior. However, these types of concern are no different than the types of issues that must be dealt with in the design of any epidemiological research program, such as the "body" of studies that purport to exonerate vaccines of safety issues routinely cited by those who feel there are no vaccine safety issues of concern. It is not necessary to delay this array of study for one or two years while a feasibility study is undertaken. Such a delay will only serve to further jeopardize public confidence in vaccine safety.

In order to further the goals suggested with regard to independence and transparency, the Institute of Medicine should not be assigned the task of feasibility or oversight of this program of research, as there is no assurance than an IOM panel will have the breadth and diversity of representation necessary to meet these goals, as well as the fact that the IOM is not required to fully comply with the Federal Advisory Committee Act, thus limiting transparency and public engagement.

We also note that portions of the Prioritization Criteria labels and defining issues have been modified and would recommend the use of the labels from the SLCWG, which appear to be more clear and neutral in tone. Some of the general principles for application of the criteria developed at the SLCWG have also been removed and we would recommend their reinstatement with particular attention to the principle

- Criteria should be applied in a transparent process with stakeholder input throughout the process to enhance accountability and enhance public trust and confidence.
- The following criteria are proposed so that prioritization decisions are made in a consistent and fair fashion.
- In order to achieve accountability, NVAC will provide an explanation of how they applied the criteria to the issues on the research agenda.

Thank you for this opportunity to offer comment. Please don’t hesitate to contact us with any questions regarding our statement.

Sincerely,

Theresa K. Wrangham,
President